IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Examiner: SWOPE, Sheridan
Nayar, Rajiv *et al.*	Art Unit: 1652
Application Serial No. 10/578,692	Confirmation No.: 3669
Filed: August 26, 2006	Attorney Docket No. ARR-0037-1.US
For: DRY RECOMBINANT HUMAN ALPHA 1-ANTITRYPSIN FORMULATION	Customer No. 77845

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF Philip J. Barr, Ph.D.
UNDER 37 CFR 1.132

I, Philip J. Barr, declare and state that:

1. I hold a B.Sc. (Hons.) degree in Chemistry from the University of Birmingham, England, and a Doctor of Philosophy degree in Chemistry from the University of Birmingham, England. I founded and am currently employed by Arriva Pharmaceuticals, Inc. My title is Chief Scientific Officer. My scientific Curriculum Vitae, along with a list of my publications, is attached as Exhibit A and forms part of this Declaration.

2. Prior to making this Declaration, I reviewed U.S. Patent Application Publication No. (U.S. Patent Application No. 10/578,692 ("the '692 patent application"). I am also familiar with the prosecution history of the '692 patent application, including the Office Action mailed on April 10, 2008 and the Final Office Action mailed March 4, 2009, in which claims 1-21 were rejected as allegedly lacking enablement and written description.

3. The claims in this application, in one aspect, are directed to dry powder compositions comprising non-glycosylated recombinant human alpha 1-antitrypsin (rAAT).

4. I understand the Examiner has asserted that the specification does not meet the enablement and written description requirements.

5. I disagree with the following statement:

> [a] person of ordinary skill in the art would not understand recombinant α1-antitrypsin to mean the protease inhibitor having the amino acid sequence shown in . . . the '311 patent and having inhibitory activity toward neutrophil elastase because: (i) the skilled artisan would know that α1-antitrypsins have activity against trypsin, chymotrypsin, anionic trypsin, chymotrypsin II, pancreatic elastases, granulocytic elastase, and acrosin . . . , as well as neutrophil elastase and, more likely than not other proteases, (ii) . . . there are a wide variety of structural proteins annotated as having α1-antitrypsin activity, and (iii) there are a variety of mutated human α1-antitrypsin proteins[.] (pages 5-6 of the March 4, 2009 Office Action)

6. For the reasons that follow it is my opinion that a person of ordinary skill in the art would appreciate that a 395 amino acid non-glycosylated recombinant human alpha 1-antitrypsin (rAAT) having an N-terminal methionine corresponds to the amino acid sequence provided in Accession Nos. P01009 and AAB59375, with the exception of an N-acetylmethionine residue at the amino terminus.

7. The pending claims recite a "non-glycosylated recombinant human alpha 1-antitrypsin (rAAT)." The specification provides that "rAAT is a 395 amino acid protein of 44 kD, that is non-glycosylated and has an amino acid sequence identical to the human plasma protein (AAT) with the exception of an N-acetylmethionine residue at the amino terminus." A search on the Protein sequence database at http://www.ncbi.nlm.nih.gov/sites/entrez?db=Protein&itool=toolbar using the search criteria "plasma AND human[Organism] AND alpha-1-antitrypsin[Protein Name]" yielded two identical hits (Accession Nos. P01009 and AAB59375), each of which provides a 418 amino acid sequence designating the signal peptide as residues 1-24 resulting in a mature 394 amino acid polypeptide. The 394 amino acid sequence was also published in Figure 1 of Rosenberg et al. Nature, 312 (5989), 77-80 (1984) and U.S. Patent No. 4,599,311. A person of ordinary skill in the art would appreciate that the rAAT referred to by the Applicants in the claims and specification corresponds to the human plasma protein (AAT) sequence provided in Accession Nos. P01009 and AAB59375, with the exception of an N-acetylmethionine residue at the amino terminus.

8. I further declare that all statements made in this Declaration of my own knowledge are true and that all statements made on information and belief are believed to be true. Moreover, these

statements are made with the knowledge that willful false statements and the like made by me are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize validity of any patent issuing based on U.S. Patent Application Serial No. 11/218,699.

Date: 09/03/09

By: _____
Philip J. Barr, Ph.D.